K100974

510(k) SUMMARY

MAY - 6 2010

Submitted By: Susanne Galin, RAC
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
(812) 339-2235 x 2296
April 2, 2010

Device:

Trade Name: Spectrum® Turbo-JeCT™ PICC Set

Proposed Classification Name: Percutaneous, Implanted, Short- and Long-Term Intravascular Catheter
21 CFR §880.5200, Product Code FOZ, LJS

Indications for Use:

The Spectrum Turbo-JeCT PICC is indicated for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSIs). The Spectrum Turbo-JeCT PICC is indicated for multiple injections of contrast media through a power injector. The maximum pressure limit setting for power injectors used with the Spectrum Turbo-JeCT PICC may not exceed 325 psi and the flow rate may not exceed the maximum flow rate indicated.

Catheter Size	Maximum Flow Rate*	Injection Pressure Limit Setting
3 Fr Single Lumen	2 mL/sec	325 psi
4 Fr Single Lumen	4 mL/sec	325 psi
5 Fr Single Lumen	7 mL/sec	325 psi
5 Fr Double Lumen	5 mL/sec	325 psi
6 Fr Triple Lumen**	7 mL/sec	325 psi

*Flow rates achieved using room temperature Omnipaque 300® contrast and verified using a Medrad Stellant® CT injector system. Omnipaque 300 has a viscosity of 11.8 centipoise at room temperature (20 degrees C). A change in temperature or viscosity of the contrast medium used will result in a change in achievable flow rates.
**Lumen #1 only.
Omnipaque 300® is a registered trademark of Amersham Health, New Jersey.

Predicate Devices: Spectrum® Turbo-JeCT™ PICC Set, 510(k) number K081690

Device Description:

The Spectrum Turbo-JeCT PICC catheters are radiopaque polyurethane peripherally inserted central venous catheters impregnated with the antimicrobials minocycline and rifampin for short- or long-term use. The devices are currently available in the following configurations: 4 Fr single lumen, 5 Fr single lumen, 5 Fr double lumen. The proposed devices add two additional configurations, more specifically, a 3 Fr single lumen catheter and a 6 Fr triple lumen catheter.

Substantial Equivalence:

The Spectrum Turbo-JeCT PICC Sets in 3 Fr and 6 Fr sizes are identical to the predicate Spectrum Turbo-JeCT PICC Sets in 4 Fr and 5 Fr sizes (cleared under premarket notification 510(k) number K081680) in terms of intended use, technological characteristics, drugs used for impregnation, impregnation process, and material which support a determination of substantial equivalence.

Test Data:

The following tests were presented to demonstrate that the Spectrum Turbo-JeCT PICC Set meets applicable design and performance requirements.

- Tensile Testing
- Flow Rate
- Cyclic Bending
- Zone of Inhibition
- Elution Profile
- Air and Liquid Leakage
- Burst Pressure
- Cyclic Pinch Clamping
- HPLC Analysis
- Stability Testing

The results of these tests provide reasonable assurance that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Susanne Galin, RAC
Regulatory Affairs Specialist
Cook, Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, Indiana 47402

MAY - 6 2010

Re: K100974
Trade/Device Name: Spectrum® Turbo-JeCT™ Peripherally Inserted Central Venous Catheter (PICC)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ, LJS
Dated: April 7, 2010
Received: April 8, 2010

Dear Ms. Galin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100974

Device Name:

Spectrum® Turbo-JeCT™ Peripherally Inserted Central Venous Catheter (PICC)

Indications for Use:

The Spectrum Turbo-JeCT PICC is indicated for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSIs). The Spectrum Turbo-JeCT PICC is indicated for multiple injections of contrast media through a power injector. The maximum pressure limit setting for power injectors used with the Spectrum Turbo-JeCT PICC may not exceed 325 psi and the flow rate may not exceed the maximum flow rate indicated.

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**Lumen #1 only.
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Prescription Use XX OR Over-the-Counter Use____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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